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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/621,086	07/15/2003	Yasuo Hirata	P/16-337	9265
2352 7590 08/22/2008 OSTROLENK FABER GERB & SOFFEN 1180 AVENUE OF THE AMERICAS NEW YORK, NY 100368403			EXAMINER SMITH, PHILIP ROBERT	
			ART UNIT 3739	PAPER NUMBER
			MAIL DATE 08/22/2008	DELIVERY MODE PAPER

Please find below and/or attached an Office communication concerning this application or proceeding.

The time period for reply, if any, is set in the attached communication.

Office Action Summary	Application No.	Applicant(s)	
	10/621,086	HIRATA, YASUO	
	Examiner	Art Unit	
	PHILIP R. SMITH	3739	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) OR THIRTY (30) DAYS, WHICHEVER IS LONGER, FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If NO period for reply is specified above, the maximum statutory period **will** apply and **will** expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply **will**, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

- 1) ☒ Responsive to communication(s) filed on 16 July 2008.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

- 4) ☒ Claim(s) 1-28 is/are pending in the application.
- 4a) Of the above claim(s) 3,6 and 17-28 is/are withdrawn from consideration.
- 5) ☐ Claim(s) _____ is/are allowed.
- 6) ☒ Claim(s) 1 and 8-12 is/are rejected.
- 7) ☒ Claim(s) 2,4,5,7 and 13-16 is/are objected to.
- 8) ☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on _____ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

- 12) ☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☐ All b) ☐ Some * c) ☐ None of:
1. ☐ Certified copies of the priority documents have been received.
2. ☐ Certified copies of the priority documents have been received in Application No. _____.
3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

- | | |
|--|---|
| 1) <input checked="" type="checkbox"/> Notice of References Cited (PTO-892) | 4) <input type="checkbox"/> Interview Summary (PTO-413) |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948) | Paper No(s)/Mail Date. _____. |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO/SB/08) | 5) <input type="checkbox"/> Notice of Informal Patent Application |
| Paper No(s)/Mail Date <u>1/18/08, 4/11/08, 5/14/08</u> . | 6) <input type="checkbox"/> Other: _____. |

DETAILED ACTION

Election

- [01] Applicant's election without traverse of species [02a] in the reply filed on 7/1/08 is acknowledged.
Claims 3,6 are withdrawn.

Claim Rejections - 35 USC § 102

- [02] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [03] The rejection of claims 1-2,8,10 as being anticipated by Flaherty (6,726,677) set forth in the Office action of 1/11/08 are withdrawn in view of the amendments of 4/11/08.
- [04] Claims 1,8 are rejected under 35 U.S.C. 102(b) as being anticipated by Sachdeva (5,607,435).
- [05] With regard to claim 1: Sachdeva discloses an endoscope system comprising:
- [05a] an endoscope having an elongated insertion unit ("tubular section 12") comprising adjoining bending ("leading end 17 of the tubular section 12 is bent or curved relative to a longitudinal axis 20 of the balance of the tubular section 12 remaining in the delivery tube 14" 6/40-43) and distal sections; and
- [05b] a guide member for guiding the insertion unit, the guide member having proximal and distal guide member ends and including a plurality of tubular members ("one or more tubular sections like tubular section 22" 7/46) having varying outer diameters (see Figure 2B), each tubular member of the plurality of tubular members having
- proximal and distal ends;

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- a guide channel of a predetermined inner diameter permitting passage of tubular members having smaller outer diameter and the insertion unit (“bore 24 formed by a wall 25 made of a material exhibiting superelastic characteristics” 7/22),
- a predetermined degree of flexibility (“sufficiently rigid superelastic material to function as a delivery tube” 7/37),
- a predetermined length, and
- a direction changing unit (“curl in one direction” 7/43) operative to change an advancing direction in which tubular members having smaller outer diameter (“curl in the opposite direction” 7/44) and the insertion unit are advanced through the guide channel (“increasing the maneuverability of the instrument 10” 7/45),
- wherein the guide member is adapted to be passed through or placed in a pipe.

[06] With regard to claim 8: Sachdeva discloses that when the insertion unit guide member is being formed, the plurality of tubular members being joined are arranged so that:

[06a] the inner and outer diameters of a tubular member located on the distal guide member end will be smaller than the inner and outer diameters of a tubular member located on the proximal guide member end (see Figure 2B);

[06b] a length of the tubular member located on the distal guide member end [is] greater than that of the tubular member located on the proximal guide member end (see Figure 2B);
and

[06c] the degrees of flexibility of the tubular members are determined so that the tubular member located on the distal guide member end are softer than the tubular member located on the proximal guide member end (“This may be accomplished by making tubular

section 22 out of a more rigid or stronger superelastic material than that used to make tubular section 12" 7/39).

Claim Rejections - 35 USC § 103

- [07] The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office action.
- [08] Claims 9,11 are rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva (5,607,435) in view of Krupa (2003/0216616).
- [09] As noted above, Sachdeva discloses a plurality of juxtaposed tubes. Sachdeva does not disclose a tool tubular member which is interposed between a tube and a braid that sheathes a periphery of the tube.
- [10] Krupa discloses an "instrument channel 410" which is interposed (see Figure 2) between a number of tubes and "a layer 404 of braided material". Krupa discloses in [0037] that
- [e]xamples of materials from which layer 404 can be formed include braid or mesh manufactured from, for example, metals, alloys, low-stretch polymers (e.g. nylon, Kevlar), fiberglass, and composites of these materials. Typically, the braid or mesh wire or thread has a round cross section, but other shaped cross-section can be used (e.g., flat, oval).
- [11] At the time of the invention, it would have been obvious to a person of ordinary skill in the art that Flaherty's invention comprise a braid for sheathing a periphery of the tube, as this is well know in the art to be a strong, flexible, and lightweight material. It is also well-known to provide a tool tubular member. A skilled artisan would be motivated to do so in order to enable endoscopic surgery.

Additional Claim Rejections - 35 USC § 103

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- [12] Claim 10 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva (5,607,435) in view of Flaherty (6,726,677).
- [13] Sachdeva discloses a tubular member, as noted above. Sachdeva does not disclose a balloon.
- [14] Flaherty discloses a balloon ("balloon 76," 14/33) that changes from a contracted state to a dilated state or vice versa is located at the middle of the tubular member; and when dilated, the balloon comes into close contact with the wall of the pipe, and the tubular member is locked at a predetermined position in the pipe.
- [15] At the time of the invention, it would have been obvious to a person of ordinary skill in the art to include a balloon at the middle of a tubular member. A skilled artisan would be motivated to do so in order to "facilitate accurate and reliable positioning" (2/59).

Additional Claim Rejections - 35 USC § 103

- [16] Claim 12 is rejected under 35 U.S.C. 103(a) as being unpatentable over Sachdeva (5,607,435) in view of Hasegawa (2002/0032365).
- [17] As noted above, Sachdeva discloses an insertion unit. Sachdeva does not disclose a drum.
- [18] Hasegawa discloses a drum and an insertion unit about which the insertion unit is wound and which has a controller, which controls the bending section, incorporated in a center, and a support for supporting the drum so that the drum can freely rotate (see Figure 17a).
- [19] At the time of the invention, it would have been obvious to a person of ordinary skill in the art to incorporate the drum of Hasegawa into the endoscope of Sachdeva. A skilled artisan would be motivated to do so in order to conserve space and enhance portability.

Allowable Subject Matter

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[20] Claims 2,4-5,7,13-16 are objected to as being dependent upon a rejected base claim, but would be allowable if rewritten in independent form including all of the limitations of the base claim and any intervening claims.

[21] With regard to claim 2: as noted above, Sachdeva discloses a tubular member through which an insertion unit is passed such that it changes direction from an axial direction of the tubular member to a lateral direction thereof (see Figure 2B). Sachdeva does not disclose a "distal cover member" attachable to the distal end, although the attachable distal cover member alone is likely an obvious difference. What is not an obvious difference is a passing direction changing opening formed in a lateral side of a distal cover member attached to the distal end of the tubular member. As noted above, the insertion unit disclosed by Sachdeva changes from an axial to a lateral direction. However, it does so by having a superelastic curvature which is "unconstrained" upon extension from the distal end of the (more rigid) tubular member (7/43). Although distal cover members with lateral openings exist (see, e.g., Flaherty in previous Office actions), it is not obvious to add one to the tubular member of Sachdeva, wherein the problem of direction change using superelastic curvature.

[22] With regard to claim 13: the Prior Art does not disclose a guide tube having a metallic braid and a tube body integrated therinto and having an outer diameter that is substantially identical to an outer diameter of the bending section mounted on a periphery of the flexible tube included in the insertion unit so that the guide tube can slide freely.

Response to Arguments

[23] Applicant's arguments have been considered but are moot in view of the new ground(s) of rejection.

Conclusion

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- [24] Any inquiry concerning this communication or earlier communications from the examiner should be directed to Philip R Smith whose telephone number is (571) 272 6087 and whose email address is philip.smith@uspto.gov. The examiner can normally be reached between 9:00am and 5:00pm.
- [25] If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Linda Dvorak can be reached on (571) 272 4764.
- [26] Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

[27]

/Philip R Smith/
Examiner, Art Unit 3739

/John P. Leubecker/
Primary Examiner, AU 3739